

## SPL R4 Common Errors as of November 2009

This document is to be utilized by SPL document authors as a reference to determine the source of common errors in SPL documents submitted to FDA.

### NDC Labeler Code SPL Documents

Error Message	Solution
The id with the root 2.16.840.1.113883.6.69 must not be associated with any other document of type "NDC Labeler Code request" with a different setId	Do not submit the same NDC labeler code in a different SPL which has a different setId.

### Establishment Registration SPL Documents

Error Message	Solution
id must not be associated with any other set id for document type "Establishment registration"	DUNS Number for registrant is associated with only <b>one</b> Establishment Registration SPL's setId.
The id with the root 1.3.6.1.4.1.519.1 along with the establishment postal code (if any) and country must match the DUNS number, postal code and country in the Dun and Bradstreet database	Ensure that the DUNS Number and address for a drug establishment is correct.
an email address is of the simple form <username>@<dns-name>	<ul style="list-style-type: none"> <li>- Enter a valid e-mail address</li> <li>- Remove spaces located before or after e-mail address that were created with keyboard space bar.</li> </ul>

### Content of Labeling & Listing SPL Documents

Error Message	Solution
If the code is not C73583, C73584, C73585, C73588, C73593, C73594, C73603, C73604, C73605, C75302, C80438, C80440, C80441 or C80442 then there must be no id.	Remove the application or citation number or application and citation number code system for products which do not have application or citation numbers.
If the marketing category code is not C73626 (bulk ingredient) or C73613 (unapproved medical gas), then there must be at least one other content of labeling section besides those with the codes 48780-1 and 51945-4.	With the exception of bulk ingredient and medical gas product SPL documents, include each section of the content of labeling (package insert or drug facts) in the appropriate SPL content of labeling section. Use the appropriate section header for each section.

Name must match the code	Use the <b>preferred</b> name and UNII in the UNII list. If UNII is not included in UNII list then request UNII via e-mail to <a href="mailto:spl@fda.hhs.gov">spl@fda.hhs.gov</a>
There is a section with the code 51945-4 (principal display panel) with a jpg file (carton/container label).	Include each representative sample of a carton/container label in a major SPL section with section heading "Package.Label Principal Display Panel. (one carton/contain label image per section)
Remove additional qualifiers (e.g. dosage form, route of administration, etc...) from product names in the product data elements section.	Remove dosage form, route of administration, etc... from the product name(s) in the product data elements section of the SPL document.
Size of image file is less than 1 MB	Reduce the size of each image file to under one megabyte (MB)
<b>General SPL Errors</b>	
<b>Error Message</b>	<b>Solution</b>
A submission must contain only the SPL file whose name ends in '.xml' and associated image files whose names end in '.jpg' .	The file extension of the SPL document should be ".xml" ( <b>lower case</b> letters only) The file extension of the JPEG image files should be ".jpg" ( <b>lower case</b> letters only)
Value of version number must be greater than the value of any previously submitted version for the same setId	Increase the document version number by one whole number.
SPL document not enclosed within a directory (folder). See section five of Step-by-Step Instructions for Creating Structured Product Labeling (SPL) Files for eLIST Drug Establishment Registration and Drug Listing.	Enclose the SPL document in a folder and upload the folder containing the file via the FDA Gateway OC portal. The path name in the Gateway field should end in the folder name, not the SPL file name.
<This submission ci1257520697672.5960@lntap02_te.1.zip is incorrectly packaged, it is a ZIP file, not a directory. See section five of Step-by-Step Instructions for Creating Structured Product Labeling (SPL) Files for eLIST Drug Establishment Registration and Drug Listing.	Remove SPL file and, if applicable, image files from the <b>zip file</b> place in a <b>single folder</b> and resubmit via FDA Gateway OC portal.

Multiple SPL files	Include only one SPL document and, if applicable, associated image files per folder.
Extra folder layers	Send the SPL files and, if applicable, associated image files in a single folder.